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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,134	08/29/2005	Steven Jones	85084-402	3937

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,134	JONES ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,13-15,17,19-23,25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 13-15, 17, 19-23, 25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 24, 2008 has been entered.

Status of the Claims

Claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 are pending and under examination. No current amendments to the claims as filed June 4, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (Journal of Virology, 1999, Vol. 73, No. 10, pages 8907-8912) in view of Kahn et al. (Journal of Virology, 2001, Vol. 75, No. 22, pages 11079-11087) **is maintained**.

The claimed invention is drawn to a recombinant vesicular stomatitis virus (VSV) particle comprising a nucleic acid molecule encoding a viral hemorrhagic fever (VHF) glycoprotein (G) inserted into the viral genome wherein the foreign G has replaced the native VSV G and only the VHF G is expressed on the surface of the recombinant VSV particle, wherein said recombinant VSV particle is infectious, wherein the VHF G is an immunogenic fragment, wherein the VHF G is from Lassa virus, Marburg virus, Ebola virus, Crimean-Congo HFV, Dengue virus, Nipah virus, Hendra virus, Machupo virus, Junin virus, Guanarito virus or Sabia virus, wherein the first gene of the recombinant VSV codes for the VHF G, and further limiting wherein the VHF glycoprotein is from Lassa virus, Marburg virus or Ebola virus.

The claimed invention is drawn to a method of eliciting an immune response in an individual comprising administering the VSV particle comprising a VHF G as described above, wherein said recombinant VSV stimulated infection but does not cause disease or symptoms associated with VHF, wherein the particle is administered orally or intranasally.

The claimed invention is also drawn to a method of preparing a pharmaceutical composition for passive immunity comprising said recombinant VSV particle as described above comprising harvesting antibodies from an animal and mixing with a suitable excipient or carrier.

Ito et al. (hereinafter Ito) teaches a recombinant VSV expressing Ebola glycoprotein wherein the mutation reduced the infectivity of the VSVΔG by incorporation

of the Ebola virus glycoprotein into recombinant VSV particles (Abstract and page 8908, 2nd column).

Ito does not teach a method of eliciting an immune response or preparing a pharmaceutical composition.

Kahn et al. (hereinafter Kahn) teaches a recombinant vesicular stomatitis virus (VSV) expressing foreign proteins that elicit specific protective immunity (Abstract). Kahn teaches the VSV glycoprotein (G) gene was deleted from the full-length cDNA VSV genomic plasmids containing the RSV G gene such that the RSV G genes replaced VSV G in viral genome (page 11081, second column). The RSV G (attachment) is the first and major antigenic glycoprotein (page 11079, last paragraph). Kahn teaches a method of eliciting an immune response in mice by intranasal vaccination with a recombinant VSV expressing RSV G (Abstract). Kahn teaches about vaccine development and passive immunization with a recombinant VSV expressing RSV G (page 11079, last paragraph). Purified RSV was harvested from baby hamster kidney cells and the antibodies were detected by ELISA after mice were inoculated intranasally with recombinant viruses (page 11080, third paragraph and page 11083, second and third paragraph).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to prepare the immunogenic composition, use it to elicit an immune response in an animal, and recover antibodies from said animal for use in passive immunization. The person of ordinary skill in the art would have been

motivated to make use a VSVΔG to elicit an immune response because Ito teaches it is effective with Ebola (VHF), and reasonably would have expected success because of the teachings of Kahn.

Response to Arguments

Applicant's arguments filed June 4, 2008 have been fully considered but they are not persuasive. Applicant argue "Kahn states that "the infectivity of these viruses is therefore based on the presence of VSV G which is supplied in trans by the BHK G cell line.' Thus, Kahn does not teach a particle in which only the VHF glycoprotein is expressed as in Kahn, Both the RSV and VSV G proteins are present." In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Ito teaches a recombinant VSV wherein the Ebola virus glycoprotein was incorporated into recombinant VSV particles. Kahn teaches a recombinant VSV expressing foreign protein wherein the RSV G replaced the VSV G (glycoprotein) in the viral genome. The combination of references teaches the instant claimed invention.

Applicants argue Yang et al. (abstract) "states that the main viral determinate of Ebola virus pathogenicity is the glycoprotein and the glycoprotein likely contributes to hemorrhage during infection." Yang et al. teaches the Zaire strain of Ebola virus is lethal to nonhuman primates and man but the Reston strain does not cause disease in humans." (page 887, 2nd column) Therefore the cytotoxicity is species specific.

Applicants argue "prior art does not teach an infectious virus particle wherein a VHF glycoprotein is the only glycoprotein present on the particle." Ito teaches "that Ebola virus GP confers infectivity to the mutant VSV" (page 8907, 2nd paragraph).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Takada et al. (Proc. Natl. Acad. Sci. USA, December 1997, Vol. 94, pages 14764-14769) teaches a recombinant VSV containing the green fluorescent protein (GFP) gene instead of the G protein gene.

Conclusion

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/

September 18, 2008
/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648